Applicant: Yu et al.

Serial No.: 10/718,986

Attorney's Docket No.: 21865-002001 / 6502

Preliminary Amendment and RCE

Filed: November 21, 2003

REMARKS

Any fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 06-1050. Applicant hereby petitions that the period for response to the action dated September 27, 2008, be extended one month to and including January 28, 2008. Payment of the requisite fee of \$60.00 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account Authorization. Please apply any other charges or credits to Deposit Account No. 06 1050. If a Petition for Extension of time is needed, this paper is to be considered such Petition. An Information Disclosure Statement is being provided under separate cover.

Claims 1-3, 6-10, 12-14, 22, 24, 31-34, 47, 50, 54-58, 61-80 and 82-98 are pending in this application. Claims 5, 16-20, 23 and 81 are cancelled herein. In the interest of advancing prosecution, Claim 1 is amended to specify that the therapeutic domain is a sialidase, and the anchoring domain binds to a glycosaminoglycan (GAG) on the surface of the target cell. Claim 1 also is amended, for the sake of clarity, as being directed to a "compound." Basis for these amendments can be found in the specification, for example, at page 4, lines 7-10 and 21-30; and at page 20, line 26 to page 21, line 30. Dependent claims are amended accordingly for proper antecedent basis and claim dependency, and/or to more distinctly characterize what is claimed.

Claim 80 is amended to incorporate the limitations of Claim 81, which is cancelled. Applicant notes that the Examiner has included Claim 80 among the claims that have been withdrawn from further consideration as being drawn to non-elected subject matter. Applicant however submits that the withdrawal is improper (*see* discussion below), and requests that Claim 80 be rejoined with the remaining pending claims.

Method claims 50, 54-58 and 82-94, directed to non-elected subject matter, are retained for possible rejoinder upon allowance of product claims deemed allowable. In the Restriction Requirement mailed May 25, 2006, The Examiner noted, and Applicant acknowledges, that method claims depending from or otherwise incorporating all limitations of allowable product claims will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Applicant: Yu et al.

Serial No.: 10/718,986

Attorney's Docket No.: 21865-002001 / 6502

Preliminary Amendment and RCE

Filed: November 21, 2003

WITHDRAWAL OF CLAIM 80 FROM FURTHER CONSIDERATION AS BEING DRAWN TO NON-ELECTED SUBJECT MATTER

In the Final Office Action (page 2), the Examiner includes Claim 80 among those that are withdrawn from further consideration as being drawn to non-elected subject matter.

Applicant respectfully submits that the withdrawal is improper, and asks that Claim 80 be examined with the remaining pending claims.

Claim 80 as amended is drawn to a delivery system containing the pharmaceutical formulation of Claim 73 and a nebulizer, an atomizer or a dropper bottle. Claims 80 and 73 are related as a combination (Claim 80) and subcombination (Claim 73). Inventions that are related as a combination and a subcombination are properly restrictable only if it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability and the subcombination has utility by itself or in other combinations (MPEP §808.05(c)). In this instance, while the pharmaceutical formulation of Claim 73 (*i.e.*, the subcombination) can be used independently or in combination with components other than those specified in the delivery system of Claim 80, the combination of Claim 80, *i.e.*, the pharmaceutical formulation of Claim 73 combined with a nebulizer, an atomizer or a dropper bottle, requires the particulars of the pharmaceutical formulation of Claim 73 for patentability. Therefore, the two-way distinctness test set forth in MPEP §808.05(c) is not met, and Applicant asks that Claim 80 be rejoined with the remaining pending claims.

* * *

In view of the amendment and remarks herein, entry of the Preliminary Amendment and RCE is respectfully requested.

Respectfully submitted,

Date: 28 January 2008 /Anita L. Meiklejohn/

Anita Meiklejohn Reg. No. 35,283

Fish & Richardson P.C. 225 Franklin Street Boston, MA 02110

Telephone: (617) 542-5070 Facsimile: (617) 542-8906 email: meiklejohn@fr.com